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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,508	01/26/2001	Susan G. Stuart	BEBIO-111 C1	8243

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1642	13

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/769,508	STUART ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2003* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The response to the restriction requirement, filed Feb. 5, 2003, is acknowledged. Upon further consideration, a new restriction requirement is set forth below.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, 19 and 42, drawn to a DNA molecule, comprising all or parts of SEQ ID NO: 1, or a DNA molecule encoding all or part of SEQ ID NO: 2, vector, host cell, and method of producing the encoded protein, classified in class 435, subclasses 69.1, 320.1, 325, class 536, subclass 23.5.

II. Claims 13-16, 36-41, 43, 52- 54, and 60 drawn to gp75 protein and fragments thereof, kits comprising the gp75 protein, or anti-idiotype antibodies, or both gp75 proteins and anti-idiotype antibodies, vaccines comprising the gp75 protein, classified in class 530, subclass 350, or subclass 387.2, and class 424, subclass 185.1.

III. Claims 17, 18, 35 and 64; drawn to antibodies to gp75, and fragments thereof, classified in class 530, subclass 387.2.

IV. Claims 18 and 59, drawn to methods for treatment, comprising administering antibodies to gp75 protein, classified in class 424, subclass 143.1.

V. Claims 20-34, 44, 45, 51 and 55-58, drawn to methods for testing for the presence of gp75, comprising using an antibody to gp75 protein, classified in class 435, subclass 7.1.

VI. Claims 46-50, drawn to methods for treatment, comprising administering gp75 protein, classified in class 514, subclass 12, class 424, subclass 131.2.

VII. Claims 44, 45, 61, 63, drawn to methods for detection or purification of c-erbB-2 ligand, classified in class 436, subclass 501.

VIII. Claims 44, 45, and 62, drawn to methods for detection of anti-gp75 antibodies, classified in class 436, subclass 503.

IX. Claims 44 and 45, drawn to methods for the detection and quantification of gp75 proteins, antibodies to gp75 and ligand to c-erbB-2, classified in class 436, subclass 63, or 64.

3. The inventions are distinct, each from the other, for the following reasons:

Groups I, II, and III are drawn to separate and distinct products. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute distinct inventions for the following reasons: The polynucleotides of group I, the polypeptides of group II, the antibodies of group III, and the anti-idiotype antibodies of group IV are chemically distinct products, and separately classified, having separate fields of search. Although the polynucleotides of group I are related biologically to the proteins of group II by virtue of the fact that the polynucleotides encode the polypeptides, the two inventions are distinct, because the protein product can be made by other, and materially different processes, such as by synthesis, or by purification from the natural source. Further, the polynucleotides may be used for processes other than the production of the protein, such as nucleic acid hybridization assays.

Although the proteins of group II and the antibodies of group III are related due to the necessary complementarity of the protein to the antibodies of group III, the inventions are distinct inventions. The proteins of group II can be used for another and materially different process than for the production of the antibodies of group III, such as methods for assaying or purifying the natural ligand of the protein, or in assays for the identification of agonists or antagonists of the proteins of group II. For these reasons the polynucleotides of group I, the polypeptides of group II, and the antibodies of group III are distinct inventions. Further, it would place an undue burden on the examiner to examine several, independent inventions in one application.

The polynucleotides of group I are unrelated to the methods of IV-IX, because none of these groups, all drawn to methods, comprise the use of polynucleotides of group I.

Groups IV-IX are drawn to separate and distinct processes. Group IV is drawn to methods for treatment comprising administering the antibodies of group III. Group V is drawn to methods of detection comprising the use of the antibodies of group III. Group VI is drawn to methods of treatment comprising administering the proteins or anti-idiotype antibodies of group II. Group VII is drawn to methods for detection of c-erbB-2 ligand. Group VIII is drawn to methods of detection of antibodies that bind to gp75. Group IX is drawn to methods of detection gp75 proteins, gp75 antibodies and detection of c-erbB-2 ligand. The methods of treatment are each distinct from each other, because they comprise the administration of different products, and thus comprise different method steps. The methods of detection are distinct from each other, because they each comprise detection of different products. Thus, groups IV-IX are separate and distinct methods, because they comprise different method steps, and result in different endpoints.

Further, it would place an undue burden on the examiner to examine several, independent inventions in one application.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of group II may be used in in vitro methods of detection or to purify antisera, which are methods that are materially different from the in vivo methods for treatment of group VI.

Inventions III and either IV or V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, there are two separate methods of use of the products of group III. The antibodies of group III may be used in in vitro methods of diagnosis and detection of group V, and also in the materially different in vivo methods for treatment of group IV.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, have recognized divergent subject matter, and because each invention requires a separate non-coextensive search, restriction for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the requirement is traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
April 16, 2003

Anne L Holleran
Patent Examiner